

PARTICIPANT INFORMATION SHEET

Principal investigator: Baukje de Roos

Study-specific research manager: Edward Payne

Name of Study: Reactivi-Tea Study

You are invited to take part in a research study. Before you decide whether to volunteer, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish.

Please do not hesitate to contact us (see below) if there is anything that is not clear or if you would like more information.

What is the purpose of this study?

The aim of this study is to understand how drinking black tea or green tea affects your attention, mood, and sleep. We also would like to monitor lifestyle factors unique to you, such as work routine or exercise, that might influence your response to drinking tea. By taking frequent measurements we will be able to identify why people respond to drinking tea in different ways, despite consuming the same products. The results from this study will hopefully help us to understand whether people do or don't benefit from drinking tea.

Why have I been chosen?

You have been chosen because you fulfil our inclusion criteria:

- You have expressed an interest in participating in this study.
- You are aged 18 years or older.
- You possess a computer, tablet, or smartphone that you can access regularly throughout any day of the week.

Do I have to take part?

Participating in this study is voluntary. If you decide to participate, we will screen you to see whether you are eligible to take part and provide you with a consent form to sign. Should you change your mind later, you can withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What does the study involve?

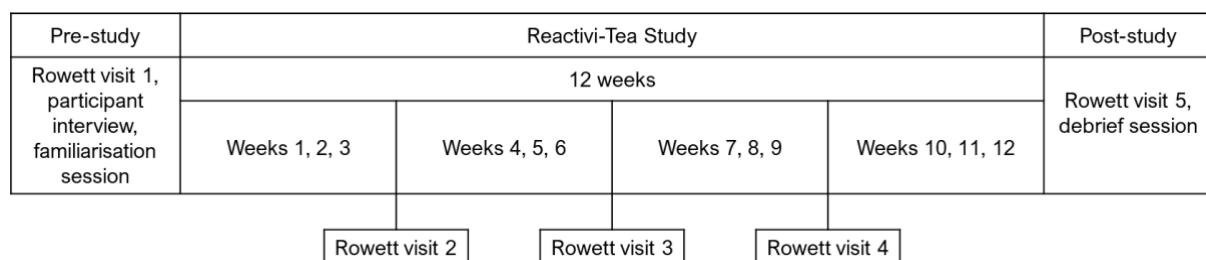
Screening and interview

To determine whether you are eligible for this study, we will ask you to complete a health screening form. This form will ask you for general personal details and ask you about your health status with regards to health conditions that would likely influence the results, but are not the focus of, this study, e.g., Alzheimer’s Disease or Parkinson’s Disease.

If you are eligible, you will be asked to complete a series of questionnaires about your general health, typical activity levels, predisposition to anxiety, tea and caffeine consumption, and sleep quality. These questionnaires should take approximately 30-45 minutes to complete. We will then arrange the first visit to the Rowett Institute prior to the start of the study where you will carry out a short interview with the researcher to find out more about your habits, discuss your tea preferences for the study, and set appropriate prompting times. This will be an opportunity for you to try the tea drinks and we will demonstrate the daily tasks and questionnaires and give you some time to familiarise yourself with them. This visit should take a maximum of 1 hour. You do not have to answer any questions you are unhappy or uncomfortable with. The personalised questions you receive during the study (more information below) will depend on your responses to the questionnaires you complete at the start of the study, together with information you provide during the interview. Therefore, the more information you give, the better we can tailor the questions delivered to you during the study.

Study schedule

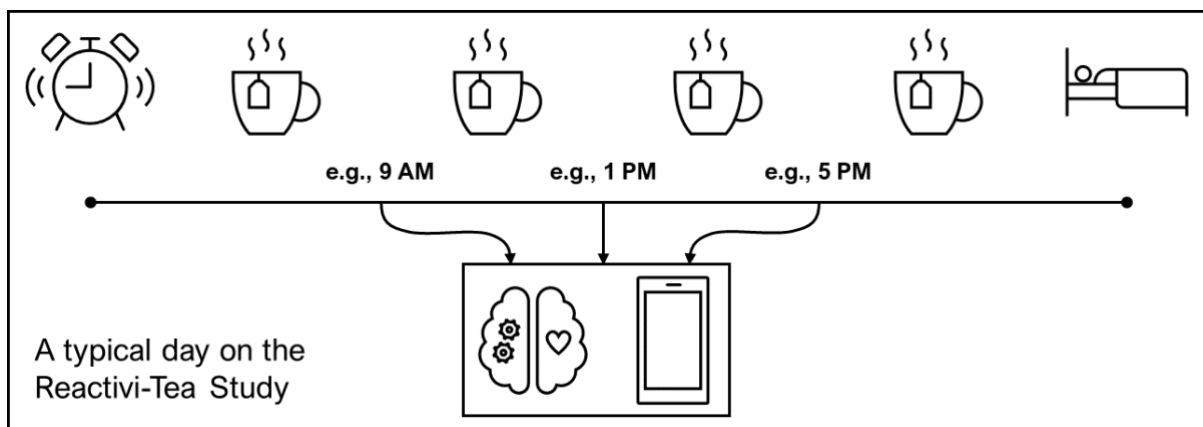
The study will last for 12 weeks (see diagram below). Each week will be assigned to one of three, regular tea or tea-like drinks, and you will be asked to consume that drink as much as you would like for six of the seven days in that week. For the duration of the study, we will ask you to refrain from consuming any other tea or caffeinated drinks. You will visit the Rowett Institute three times during the study to collect your drink allocation for the next three weeks and exchange the wearable we will use to prompt you throughout the study. At the interview prior to the start of the study, we will arrange a time and preferred method with which to contact you each week, to ask how you are getting on with the measurements and answer any questions you may have.



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Daily tasks and questionnaires

Three times per day (as set during the initial interview), on every day of the study, you will be prompted to complete three or four short questionnaires and two cognitive tasks, which should take approximately 5-10 minutes to complete. The questionnaires will ask you about your sleep the night before (once per day), tea consumption so far that day, lifestyle factors identified before the study, and your current mood. The cognitive tasks will assess your attention. During one task, the digit vigilance task, you will be shown a target digit on the right of the screen and a stream of random numbers between one and nine on the left of the screen. You will be asked to respond when the numbers match. During the other task, the attention switching task, you will be shown consecutive pairs consisting of one letter and one number, both in either red or purple. There are two conditions for responding during this task: if the font colour is red and the letter is a vowel, or, the font colour is purple, and the number is even. In other conditions, you will be asked to withhold your response.



We will be using a web-based test platform to deliver the tasks and questionnaires called Gorilla Experiment Builder (Gorilla Experiment Builder - Easily Create Online Behavioural Experiments). While they will collect the data (responses) you provide during the tasks and questionnaires, they do not have control of the data – the University of Aberdeen research team have control of the data.



The PRO-Diary wearable device

You will also wear a wrist-worn device each day, called a PRO-Diary. The device monitors your activity levels and sleep quality through measuring movement. It also delivers prompts, via a

beep or a buzz and text accompaniment, to remind you to complete the questionnaires and cognitive tasks.

For the entire duration of the study, you will be expected to wear the PRO-Diary device and complete the questionnaires and cognitive tasks daily, or as often as you can. The more responses you give, the better we will be able to examine which personal factors affect your responses to drinking tea.

Visits to the Rowett Institute

As well as the pre-study meeting and visits to collect your tea allocation, the Rowett visits will also be an opportunity to discuss any issues with compliance to the daily questionnaires and cognitive tasks that may have arisen since the last visit. The fifth (final) visit will be to return the PRO-Diary device.

What will happen to the responses I give?

All responses to the questionnaires and cognitive tasks, and activity data we receive from the PRO-Diary devices you use will be coded to ensure anonymity. Responses and device data will only be accessible by the University of Aberdeen research team, and will not be shared with, or stored by, the company providing funding for this study. Results will be produced from data collected during this study that will be completely anonymous and will likely be published in a publicly available journal. The responses you give and the data you provide will be stored on university servers until the 30th of November 2029. This is to conform with the University of Aberdeen Research Data Management policy that states in article 13.2 'In any case, data should be retained for a minimum of 5 years from project end date'.

How will I be reimbursed?

You will receive a total of £125 upon completion of the study as a contribution towards travel costs and your time spent taking part in the study.

What are the possible benefits of taking part in the study?

By taking part in this study, you will receive insights into your attention, mood and sleep patterns, and how drinking tea may affect these outcomes for you personally. The information we obtain from this study will inform us about how personalised factors can affect health and wellbeing and enable us to better tailor individual dietary interventions in the future.

What are the possible disadvantages and risks of taking part in this study?

The study duration and regularity and frequency of the testing may cause you to feel increased levels of stress. We hope to reduce the likelihood of this happening by maintaining regular contact with you throughout the study and providing you with a study-independent contact (Dr Frank Thies) below should you wish to speak to someone not involved with the study.

What if there is a problem?

If you have a complaint about your treatment during the study, or any possible harm you might suffer, please get in contact with one of the investigators (Edward Payne or Baukje de Roos) as soon as possible and we will try to address the problem immediately. If you would prefer to speak to an independent person, please feel free to contact Dr Frank Thies, on +44 (0)1224 437954 or at f.thies@abdn.ac.uk.

Who has reviewed this study?

This study has been reviewed and approved by the Human Studies Management Committee and the Rowett Ethics Committee.

Who is organising and funding the research?

This study is organised by the Rowett Institute. The research is funded by Lipton Teas and Infusions, and they will be providing the tea products for this study. Lipton Teas and Infusions will not be involved in the data analysis nor in the interpretation of results. They may want to use the results of this study to improve the marketing of their tea products in the future.

Will my taking part be kept confidential?

Yes. All of your data will be coded and stored in lockable cabinets or on University of Aberdeen password-protected computers and shared drives; this data will not be made available to Lipton Teas and Infusions. The code that can link the data to you will be stored separately. Any publications arising from these data will not identify you as a participant. Any individualised questions or responses will be referred to using minimal non-identifiable characteristics such as age and gender only.

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STUDY CONTACTS

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